

Existing Approaches for Evaluating the Health Effects of Functional Foods

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INTRODUCTION

- Bioactive food components obtain much attention.
- Many food products are already on the market with health claims.
- Increasingly documented effects of dietary components on body functions.
- EC regulation on health claims in preparation.
- No harmonized global approach.

INTRODUCTION AND EUROPEAN NEEDS

- No harmonized approach for scientific substantiation of claims.
- No European/EC regulation on health claims in 2000.
- New draft EC regulation on health claims appeared in 2001.
- Revised draft EC regulation on health claims in 2003.

Functional Foods Task Force

Publications

EC

International Organisations

International Symposium



Proceedings



Report



Concise Monograph



ITG 1



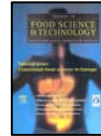
ITG 2



Consensus



Technology



ITG



Consensus



1995



1996



1997



1998

1999

2000

2001



2002



2003



2004



2005

F U F O S E

P A S S C L A I M



C o d e x

C C F L



EC-DG Sanco



Codex Asia



Codex CCNFSDU



Council of Europe

FUFOSE: From evidence based on markers for functional foods to types of claims relevant to them

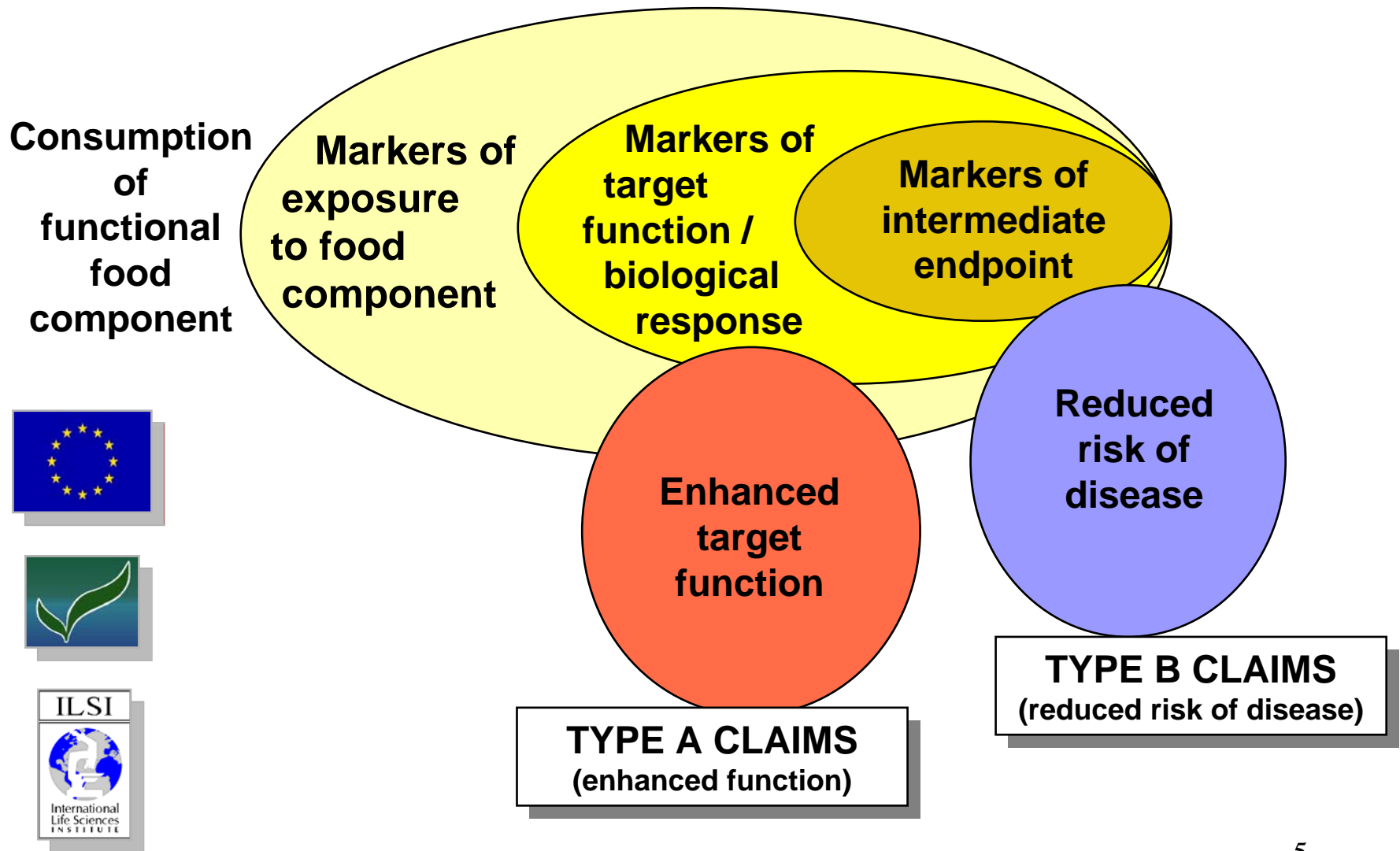


Table 1 - Health claims classification according to FUFOSE, Council of Europe, Codex Alimentarius and the proposed EU regulation

FUFOSE (1998)	Council of Europe (2001)	Codex Alimentarius (2003)	Proposed EU regulation (2003)
Nutrient function claims not considered ----- A. Enhanced function claims	Nutrient function claims not considered ----- A. Enhanced function claims	Nutrient function claims ----- Other function claims	Health claims related to the generally accepted role of nutrients and other substances
B. Disease risk reduction claims	B. Disease risk reduction claims	Disease risk reduction claims	Health claims related to disease risk reduction

Nutrient function claims (sometimes referred to as structure function claims), enhanced function claims, and other function claims are closely related, but have been introduced at different stages of the claim development discussion. The dotted lines indicate that there is no absolute delimitation between “nutrient function claims” on the one hand and “enhanced function/other function claims” on the other hand. A “new” function of a nutrient may be regarded as an enhanced/other function until, through further documentation, practice and familiarity; it becomes generally recognised as a “nutrient function claim”. A function of a non-nutrient would be regarded as “other function” according to Codex, but as science advances, it may later fall under “generally recognised effects of nutrients and other substances” according to the proposed EU regulation [1].



Process for the Assessment of Scientific Support for Claims on Foods

PASSCLAIM

A European Commission (EC) Concerted Action
Coordinated by the International Life Sciences Institute
ILSI Europe



Project Management Team

Project co-ordinator

- Dr. Laura Contor, ILSI Europe, (B)

Project supervisor

- Dr. Daphne Pannemans, ILSI Europe, (B)

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Project Management

Steering Committee

- Prof. N. Asp, University of Lund (S) -Chair-
- Prof. P. Aggett, University of Central Lancashire (UK)
- Dr. F. Bellisle, INSERM (F)
- Prof. G. Rechkemmer, Technische Universitaet Muenchen (D)
- Dr. J-M. Antoine, Groupe Danone (F)
- Dr. B. German, Nestlé (CH)
- Dr. D. Müller, Procter & Gamble (D)
- Dr. H. Verhagen, Unilever (NL)
- Dr. L. Contor, ILSI Europe (B)

Scientific Support for Claims

PASSCLAIM



...builds upon the **FUFOSE** project

... suggested that claims for '*enhanced function*' and '*reduced risk of disease*'

...should be based on well-designed studies using appropriately-identified, characterized and validated markers.



Principal Objectives

- To evaluate existing schemes which assess scientific substantiation;
- To produce a generic tool for assessing the scientific support for health claims for foods;
- To establish criteria for markers which can be used to explore the links between diet and health.



Participation in figures

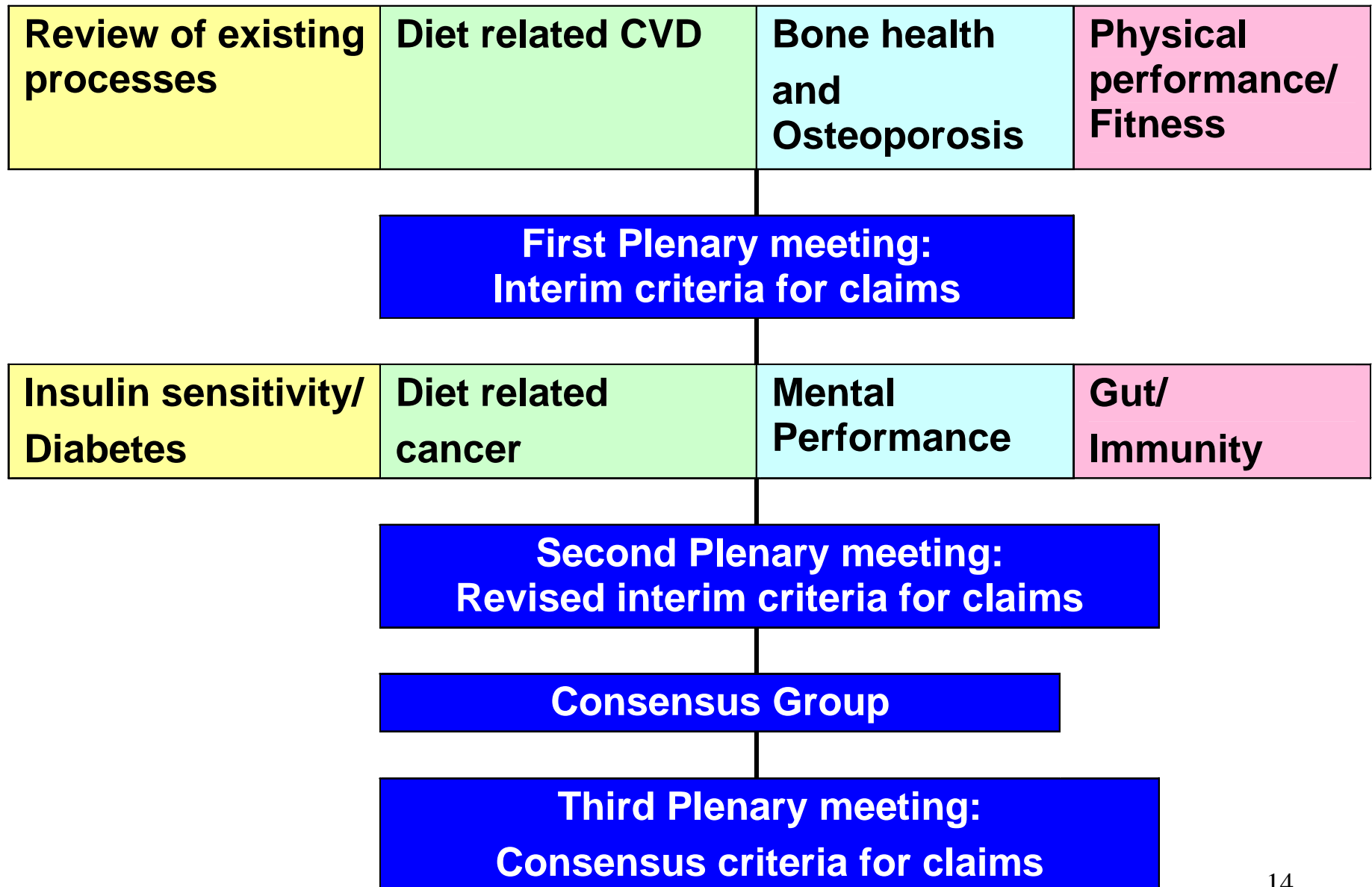
- 58 scientists from industry
- 42 scientists from universities
- 66 scientists from research institutes
- 24 countries represented



Steps followed

- Collate potential types of claims.
- Describe scientific support needed and evaluate relevance.
- Assess usability and validation of markers.
- Develop list of criteria to evaluate the substantiation of claims.

Schematic Representation of the Project



ITG's & Chairs

ITG A: Diet related atherosclerosis: Prof R. Mensink (NL)

ITG B: Bone health and osteoporosis: Prof A. Prentice (UK)

ITG C: Physical performance & fitness: Prof W. Saris (NL)

ITG D: Review of existing schemes in different countries to substantiate the scientific basis for claims:
Prof D. Richardson (UK)

ITG's & Chairs (cont'd)

ITG E: Insulin sensitivity & diabetes risk: Prof. G. Riccardi (I)

ITG F: Diet-related cancer: Prof J. Rafter (S)

ITG G: Mental state & performance: Prof J. Westenhoefer (D)

ITG H: Gut health and immunity: Prof J. Cummings (UK)



First PASSCLAIM publication on Phase One: Preparing the Way

Published in the *European Journal of Nutrition* (Vol. 42 Suppl. 1 March 2003).

Second PASSCLAIM publication on Phase Two: Moving Forward

Published in the *European Journal of Nutrition* (Vol. 43, Suppl. 2, June 2004).

Criteria for the Scientific Substantiation of Health Claims

The criteria:

- emphasize the need for direct evidence of benefit to humans in circumstances consistent with the likely use of the food in order for a case to be made;
- recognize the usefulness of markers of intermediated effects when ideal endpoints are not accessible to measurement
- stress the importance of using only those markers which are of proven validity; and
- highlight the necessity of ensuring that the magnitude and character of effects on which claims are based are statistically and biologically meaningful.

Criteria for the Scientific Substantiation of Health Claims

1. The food or food component to which the claimed effect is attributed should be characterized
2. Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:
 - a) Study groups that are representative of the target group
 - b) Appropriate controls
 - c) An adequate duration of exposure and follow up to demonstrate the intended effect
 - d) Characterization of the study groups' background diet and other relevant aspects of lifestyle
 - e) An amount of the food or food component consistent with its intended pattern of consumption
 - f) The effect of the food matrix and dietary context on the functional effect of the component
 - g) Monitoring of compliance with intake of food or food component under test
 - h) The statistical power to test the hypothesis

Criteria for the Scientific Substantiation of Health Claims (continued)

3. When the true endpoint of a claimed benefit cannot be measured directly studies should use markers
4. Markers should be:
 - biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known
 - methodologically valid with respect to their analytical characteristics
5. Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported
6. A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence



Criteria for the Scientific Substantiation of Health Claims

SUMMARY: The Criteria

- Establish use of human intervention data as a key requirement
- Recognize usefulness of markers
- Stress importance of markers of proven validity
- Highlight effects must be meaningful

Table 2. Categories of evidence that may be used in the substantiation process.

Intervention Randomised controlled trials Clinical trials Physiological and psychological trials
Observational Prospective (cohort) Cross-sectional (analytical) Case control
Supporting Animal <i>In vitro</i> cell and molecular Studies of genotype Modelling (of mechanism)

In all human studies the following factors should be considered and addressed when relevant:

- Age
- Gender
- Ethnic origin
- Genotype relevant to the function under study
- Lifestyle factors, for example - smoking, physical activity, alcohol consumption
- Body weight and height
- Menstrual cycle
- Usual diet
- Environmental conditions such as climate



Third PASSCLAIM publication on Criteria
To be published in the *European Journal of Nutrition* in 2005.

Developments for which the PASSCLAIM project has been of key importance

European Commission

Working document SANCO, July 2003

Final Proposal for:

Regulation of the European Parliament and of the Council on Nutrition, Functional and Health Claims Made on Foods



PASSCLAIM EXPECTED ACHIEVEMENTS

- Propose consensus criteria to assess the scientific support for claims on foods.
- Assist those making claims and regulating claims.
- Improve the credibility of claims for consumers.
- Offer a practical scientific framework to prepare scientific dossiers supporting claims.

RESEARCH AREAS TO BE CONTINUED

- Biomarker research and validation of markers against endpoint
- Determinants of obesity
- Research on relation between food and mental performance
- Nutritional intakes and requirements



More information on PASSCLAIM

<http://europe.ilsil.org/passclaim>

THANK YOU